



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0639]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the eligibility criteria and the process to be followed by establishments when notifying FDA of a manufacturer's intent to have an accredited third party conduct a quality systems regulation inspection of their establishment instead of FDA, under the Accredited Persons (AP) Inspection Program.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program (formerly Requests for Inspection Under the Inspection by Accredited Persons Program)--(OMB Control Number 0910-0569)--Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled "Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007." This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm>. This guidance is intended to assist device establishments in determining whether they are eligible to participate in the AP Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 20 of these manufacturers may use an AP in any given year.

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity/21 U.S.C. Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Notification regarding use of an accredited person--374(g)	20	1	20	15	300

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.